REMARKS

I. Claim Rejections - §102

Claims 1 and 19 are rejected as being anticipated by the Sharma et al. publication 2004/0106956.

Sharma is directed to discriminating between arrhythmias, specifically between a ventricular tachycardia (VT) and a supraventricular tachycardia (SVT). This is important because, while an SVT can cause fast ventricular rates, a therapy delivered to the ventricles is ineffective in treating an SVT. See paragraph [0004].

According to Sharma, after ATP is delivered, the system monitors the time before an intrinsic heart beat is sensed. If the time is longer than a predetermined time window, the tachycardia is classified as a SVT. The premise is that the ATP would place the AV node in a refractory condition and only an intrinsic heart beat originating in the ventricle would be sensed within the window because the pulse does not have to travel through the AV node. See paragraph [0022].

Timing diagrams illustrating the discrimination between VT and SVT is shown in Figs. 3A and 3B.

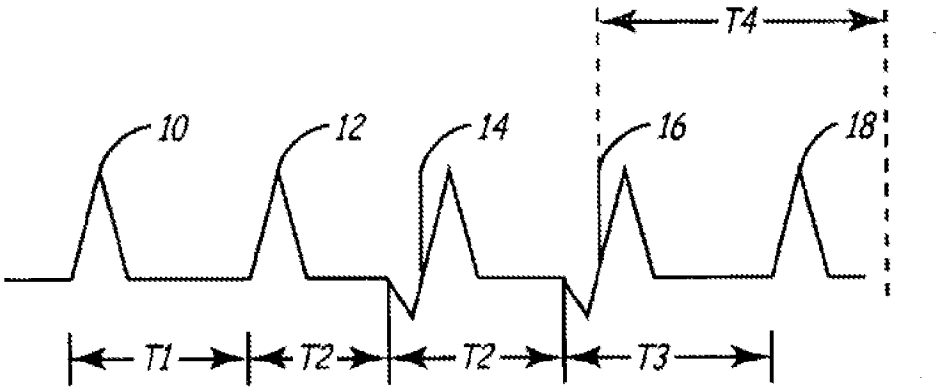

FIG. 3A

Cardiac depolarization pulses 10 and 12 indicate an on-going VT or SVT. After detection of the arrhythmia, ATP pulses 14 and 16 are delivered. After delivery of the ATP, the elapsed time between the delivery of pulse 16 and the next intrinsic pulse 18 (T3) is determined. The elapsed time T3 is the Return Cycle Length (RCL). If T3 is less than T4, as shown, the pulse 18 corresponds to a VT event. See paragraph [0055].

On the other hand, Fig.. 3B illustrates the situation where T3 is greater than T4, which indicates a SVT event. See paragraph [0056].

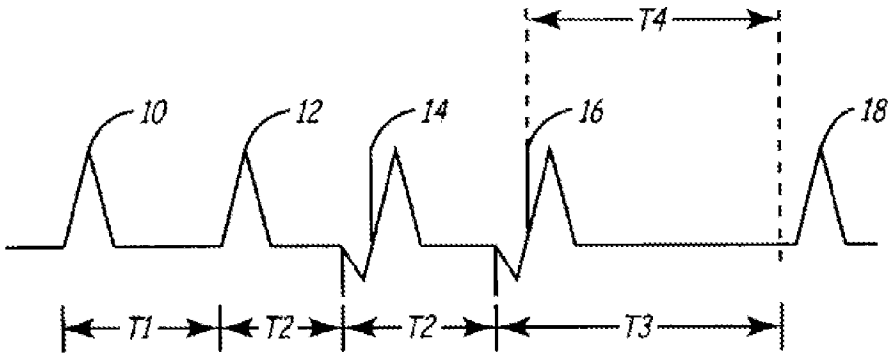

FIG. 3B

The methodology of discrimination is set forth in the flowchart of Fig. 4 as follows:

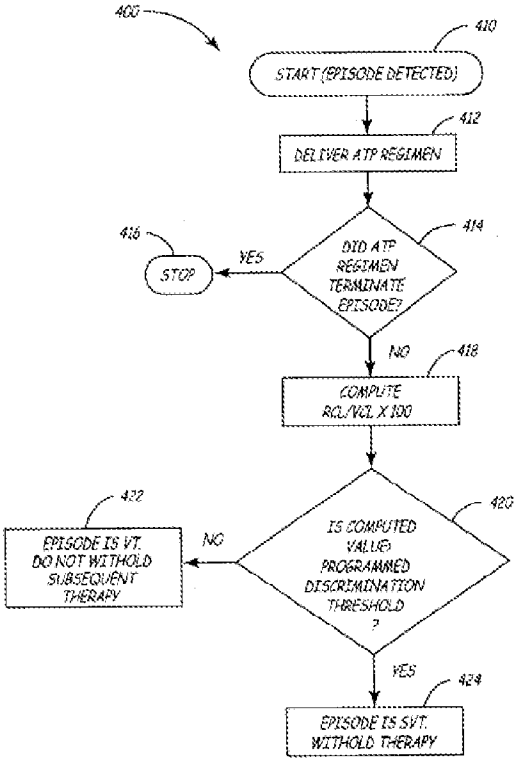

FIG. 4

As shown there, when a tachyarrhythmia episode is detected, an ATP regimen is delivered. Once delivery of the ATP is completed, the normalized RCL is computed at 418, which corresponds to T3 in Figs. 3A and 3B. Then T3 is compared to the programmed threshold to determine if T3 is greater. If T3 is not greater, as in Fig. 3A, the event is determined to be a VT. If T3 is greater, as in Fig. 3B, the vent is determined to be a SVT.

Applicant previously pointed out that Sharma fails to disclose delivery of an exploratory ATP, measuring the exploratory ATP Return Cycle Length (RCL), formulating an ATP regimen **having ATP parameters defined as a function of a measured exploratory RCL** and delivering the formulated ATP regimen to the heart chamber. In response, the examiner counters that "formulating" can mean to determine whether to apply a particular ATP regimen, even if the ATP regimen

is not new or modified. The examiner appears to be saying that since Sharma discloses that one of the possible VT therapies is ATP and determination of a VT requiring therapy delivery is made based on the RCL of an exploratory ATP, then Sharma discloses an IMD that "formulates an ATP regimen as a function of the measured RCL." What the examiner overlooks is the requirement in claims 1 and 19 that the formulated and delivered ATP therapy must also have ATP parameters defined as a function of the measured exploratory RCL. The rejection and the examiner's comments fail to address this aspect of the claims. And in fact, Sharma does not disclose that any subsequent ATP therapy that is delivered, whether new or modified, has ATP parameters that are established as a function of the measured exploratory ATP RCL.

Thus, the Sharma publication does not anticipate and the rejection should be withdrawn.

Claims 1 and 19 are also rejected as being anticipated by DeGroot (US 6,167,308).

DeGroot discloses a tiered therapy device wherein ATP therapy is first delivered and, if there is no increase in the RCL, the next scheduled therapy is delivered, which is either a new ATP regimen with different parameters or a high energy cardioversion shock. Applicant advanced the argument that DeGroot does not anticipate because the device does not formulate a new ATP regimen having ATP parameters defined as a function of the measured exploratory RCL.

In response, the examiner counters that the broadest interpretation of "formulate" includes selection of which ATP regimen to apply regardless of how the ATP parameters are defined. According to the examiner, because DeGroot selects which ATP regimen to apply based on measured RCL, the IMD is considered to "formulate an ATP regimen as a function of the measured RCL." Yet again, however, the examiner is misunderstanding that the specific recitation in claims 1 and 19 is that it is the ATP parameters of an ATP regimen that are defined as a function of the measured exploratory RCL. This is absent in DeGroot. The claim does not merely specify that a different ATP therapy regimen

is invoked based upon the measurement of the RCL of the preceding ATP therapy regimen.

In contrast to the present invention, DeGroot has no exploratory ATP regimen. DeGroot begins with a first ATP therapy regimen having pulses separated by T2, which is a function of the duration of the intervals T1 between the preceding R-waves during the tachycardia as shown in Fig. 1. See col. 2, lines 43-52.

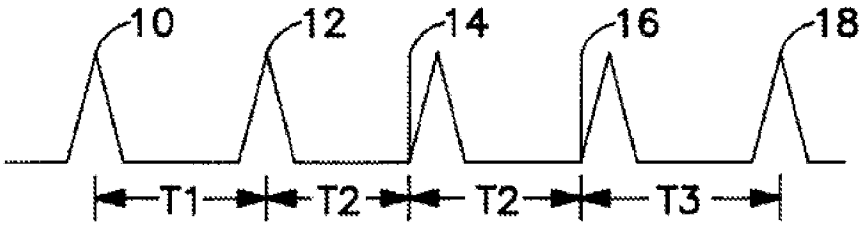

FIG. 1

The first ATP therapy regimen with T2 pulses is suspended and the return cycle length T3 is measured. The first ATP therapy regimen with T2 pulses is resumed and then again suspended to measure the RCL (T4). See Fig. 2.

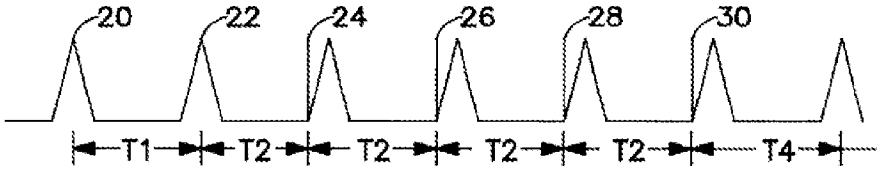

FIG. 2

The RCL of T4 is then compared to the RCL of T3. If T4 is not greater than T3, then a new ATP regimen having an inter-pulse interval somewhat less than T2 is initiated. See col. 2, line 66 to col. 3, line 3. Thus, in DeGroot, as to any new or modified second ATP therapy regimen that is initiated, the ATP parameters (e.g., the inter-pulse interval) are established as a function of the interval T2, which in turn is established as a function of the tachycardia interval T1. The ATP parameters are not a function of the measured RCL of an exploratory ATP

regimen. And, even if the first ATP therapy regimen in DeGroot is characterized as being an "exploratory" ATP regimen, it remains that according to DeGroot, the inter-pulse interval of any subsequent ATP therapy regimen is established as a function of the interval T2 of the first AT therapy regimen and not the measured interval T3 or T4.

Thus, DeGroot does not anticipate and the rejection should be withdrawn.

II. Claim Rejections - §103

Claims 2-18 and 20-38 are rejected as being obvious from DeGroot in view of Sun et al. (US 6,400,986). The rejection is premised on DeGroot teaching to formulate an ATP regimen having ATP parameters defined as a function of a measured exploratory RCL. As discussed above, that characterization of DeGroot is in error. Accordingly, the obviousness rejection of claims 2-18 and 20-38 is necessarily flawed and should be withdrawn.

III. Conclusion

Applicant submits that all claims are patentable over the prior art cited and that the application is in condition for allowance. An early action to that effect is courteously solicited.

Respectfully submitted,

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Date

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